REMARKS

Claims 1-38 were previously pending in the present application, following the cancellation of mis-numbered claim 39.

The previously pending claims overcame the previously cited novelty rejections, such that only obviousness type rejections remain. These rejections are based on an array of nine prior art references, including the newly cited Dann et al. patent.

To simply and reduce the number of issues for consideration, these claims are hereby canceled, in favor of new claims 40-58 now pending. Furthermore, the specific claim objection and rejections stated in paragraphs 2 and 4-18 of the above-reference Office action, respectively, have been considered and are believed to be both rendered moot and fully overcome by the new claims presented above.

Thus, the following remarks, of which consideration is respectfully requested, support the patentability of the pending claims, which are addressed below relative to the prior art of record rather than the specific rejections cited in the Office action. Also, before the new claims are addressed specifically, applicants ask the Examiner to reconsider the appropriateness of the combination of art suggested in the Office action.

Art Combination

Of the nine patents which constitute the foundation for the rejection of the previously pending claims, only the DeVries, Banys et al. and Markham patents teach aspiration biopsy devices. The remaining patents pertain to syringes (Dann et al, Dysarz, Lo Duca and Weis-Fogh) and catheters (Visconti and Ellingson et al.). Thus, it is important to note as an initial matter that, since biopsy devices function differently than both syringes and catheters, they naturally have different characteristics and constructions.

The Office inherently recognized this distinction by using a biopsy device reference, as the base reference for the rejection of the previously pending claims, and then borrowing certain features from the syringe and catheter art. The position

then was that the cited combinations of biopsy devices and syringes or catheters rendered obvious the invention recited in the previously pending claims. For example, the Office rejected previously pending claim 1 based on the combination of the DeVries and Dann et al. patents, essentially taking the position that it would have been obvious for one of skill in the art to incorporate the needle 8 with the bent proximal end 17 disclosed in Dann et al. into the DeVries biopsy device.

However, under the current standard for obviousness, there must be a motivation or suggestion in the references to make the combination. Applicants respectfully assert that there is no such motivation. The reason for this is grounded (1) in the vastly different application of the Dann et al. device and the other syringe/catheter art, and (2) the entirely different solutions to the problem of specimen collection proffered by DeVries and the other biopsy device art.

1. Dann et al. and other syringe/catheter art

Beyond the basic differences in function and use between biopsy devices and syringes or catheters, Dann et al. teach a use of the bent needle 8 that is completely different from, and in fact contrary to, addressing the problem of specimen reflux. More specifically, Dann et al. disclose at col. 3, lines 3-9 that the bent proximal end 17 of the needle 8 is used to:

> ... bring the proximal tip of the needle close to or in contact with the inner wall of neck 5, thereby permitting a small droplet of aspirated blood 18 to be held by surface tension between the wall of the ampule and the end of the needle and thus be visible to the user of the syringe.

The purpose of this is explained at col. 1, lines 26-40 in that when:

> ... using an injection syringe it is common practice, after inserting the needle, to aspirate a small amount of tissue fluid to determine whether or not the needle has penetrated a blood vessel. If it has, a droplet of blood is drawn into the ampule. This droplet must be immediately visible if the determination is to be useful...

From this it is quite apparent that Dann et al. are not concerned with collecting specimen of sufficient quantities for diagnostic purposes, and particularly by preventing specimens from entering the syringe itself and refluxing back into the needle. Instead they are dealing with the problem of how to make an "extremely small droplet of aspirated blood" (col. 1, line 58-59) in the syringe visible to the user, particularly in an opaque environment. Thus, Dann et al. provide no suggestion for preventing specimens from entering the syringe. Nor are Dann et al. concerned with the particular problem of reflux into the needle. This is made most evident in the paragraph beginning at col. 1, line 60, which states that "[i]t is an additional object of our invention to provide a syringe from which aspirated blood may be completely expelled, thus permitting a further trial insertion." Thus, Dann et al. not only fail to address the reflux problem, they tout that their device can readily expel the aspirated material, thus directly teaching away from the combination.

As such, from the Dann et al. disclosure one of skill in the art would not expect that the bent proximal end of the needle be useful in reducing reflux of specimen into the needle. This is even more the case given that Dann et al. disclose that the bent end is located very near the bottom of the ampule such that any accumulated specimen could easily be reintroduced into the needle.

None of the other cited prior art patents (Dysarz, Visconti, Ellingson et al., Lo Duca and Weis-Fogh) in the syringe and catheter art addresses the issue of specimen loss through reflux, which as mentioned, is not surprising given that it is a concern generally limited to aspiration biopsy devices.

2. DeVries, Banys et al. and Markham

In addition, the three references disclosing biopsy devices (DeVries, Banys et al. and Markham) address collecting diagnostically suitable specimen samples in ways other than as provided by the present invention, and further, none of them address the problem of reflux of the specimens back into the needle.

Both DeVries and Markham focus on controlling the vacuum to prevent the collected specimens from being diluted by unwanted material or from being passed

from the collection site into the syringe barrel, specifically by using a means for releasing the vacuum after the specimens are collected.

DeVries uses an O-ring 60 that can be rolled back to expose a radial port 72 to vent the interior of the hub 40 to ambient air and thereby disrupt the vacuum. The vent port does not constitute part of the passageway for the sample specimens, which instead extends from the central tapered passage 62 to the central opening 64 that receives the needle 70. The specimens are thus drawn through the needle and directly up into the hub 40 through the passage 62 and opening 64. By breaking the vacuum after the specimens are collected and before the needle is withdrawn from the sample site, unwanted tissue or fluids are not introduced into the specimen sample.

Markham uses a conventional needle 36 that has a widened female end that mounts onto a male end 34 of a stopcock body 30. Withdrawing the piston 22 creates a vacuum that extends through to the tip of the needle when the valve member 40 is opened such that the specimens enter the collection area, which is the female end of the needle, directly from the bottom. Closing the valve member before the needle is withdrawn from the sample site breaks the vacuum and prevents specimens from passing up into the valve or syringe barrel 12.

Unlike DeVries and Markham, the Banys et al. device does not have a vacuum break or a separate specimen collection area, but instead draws the specimen directly into the syringe barrel. Banys et al. are concerned primarily with providing a rapid vacuum and one-hand use using a spring loaded syringe plunger and also control of the needle opening 28 by using a retractable cannula 14 mounted coaxially over the needle 16.

Thus, none of the prior art biopsy devices address, or even identify, the problem of reflux of specimen into the needle, and moreover, none of them suggest in any way the solution provided by the present invention.

Accordingly, there is a clear lack of motivation or suggestion in the prior art to combine the prior art biopsy devices with the Dann et al. device. And further, the

disclosure of the Dann et al. patent would direct one of skill away from such a combination in that it is expressly designed for very small amounts of aspirated material and to readily expel the aspirated material back through the needle.

Applicants now address the specific claims presented above. The text of each pending independent claim has been reproduced below for convenience.

Claim 40

40. (new) A high specimen yield anti-reflux head for a needle aspiration biopsy device, comprising: a specimen collection well with a floor at its bottom and a sample passageway defined by at least one of an internal passage and a needle, the sample passageway communicating with the collection well through an internal opening in spaced relation to the floor such that a specimen can pass through the sample passageway and be deposited in the collection well from above the floor with collected specimens being spaced from the internal opening.

Claim 40 recites an anti-reflux head for a biopsy device including a specimen collection well and a sample passageway defined by an internal passage and/or a needle. The sample passageway communicates with the collection well through an internal opening spaced from the floor of the well such that the specimens are deposited in the well from above the floor and the collected specimens are spaced from the internal opening. The device of the present invention thus effectively provides a one-way functional valve that readily permits aspirated material to be deposited in the collection well while preventing reflux back flow into the needle as well as flow under suction into the syringe. Such a device is not taught by the prior art.

Applicants disclosed in paragraph 46 with respect to one preferred embodiment of the FNAB device that, "the specimens are deposited down into the collection well 64 from near the top of the well through the side opening 74, which is spaced longitudinally from the floor 66 of the collection well 64." In discussing the collected specimens, the applicants stated at the end of paragraph 51 that:

> The collection well 64 is large enough to accumulate a diagnostically sufficient quantity of specimens without reaching the height of the side opening 74. The collected specimens are thus spaced from the path back to the needle 22. This, and the fact that the specimens would have to travel sideways relative to the needle 22 (thus without the assistance of gravity) to pass through the lateral segment 76, prevents loss of specimen into the syringe barrel and by reflux back into and through the needle.

Thus, claim 40 is supported by applicants' original disclosure and recites a device that is not found by any single prior art reference of record or in any proper combination thereof.

The cited prior art references discussed above do not alone or in combination teach a device for depositing specimen into a collection well through an opening spaced from where the specimens are collected. DeVries, for example, certainly does not in that the specimens are drawn from the needle straight into the collection area such that the collected specimens would pile up from the bottom up. The collected specimens are thus in direct communication with, and in fact adjacent to and cover, the opening to the needle. Specimens can thus be readily pulled back into the needle under suction or simply by the force of gravity.

Combining Dann et al. with the biopsy art, such as DeVries, does not arrive at the invention as now recited in claim 40 because the proximal end of the needle is disclosed to be located at the bottom of the ampule, and perhaps more importantly the proximal end of the needle is adjacent to the aspirated material. This is clearly shown in Fig. 1 of the Dann et al. patent which shows the aspirated blood droplet 18 "held by surface tension" between the neck 5 of the ampule and the needle at 17.

For this, and other reasons, the invention as defined by claim 40 is believed to be patentable and not rendered obvious by the prior art.

Claim 47

47. (new) A high specimen yield anti-reflux head for a needle aspiration biopsy device, comprising: a sample passageway communicating specimens through an internal opening to a collection well where specimens are collected, the sample passageway being resistant to reflux under gravity of the collected specimens back into the sample passageway due to at least one of the configuration of the sample passageway and the location of the internal opening relative to a floor of the collection well.

Claim 47 recites that the sample passageway is resistant to reflux under gravity due to the configuration of the sample passageway and/or the location of the internal opening (through which the specimens enter the collection well) relative to the collection well floor. The device thus creates a functional valve effect during the aspiration biopsy procedure.

Again, and with reference to the preferred embodiments disclosed by applicants, the language quoted above in the discussion of claim 40 is relevant here. Specifically, the internal opening 74 to the collection well 64 is spaced from the path back to the needle 22, and this "and the fact that the specimens would have to travel sideways relative to the needle 22 (thus without the assistance of gravity) to pass through the lateral segment 76, prevents loss of specimen into the syringe barrel and by reflux back into and through the needle." This holds true for the embodiments shown in Figs. 3 and 16 in which the sample passageway is formed in part by the lumen of the needle and the internal channel 72/72C of the hub, and for the embodiments shown in Figs. 10 and 15 in which the entire sample passageway is defined by lumen of the needle.

Thus, the spacing of the collected specimen from the opening through which the specimens enter the collection well inhibits reflux of the specimen back into the needle, since gravity would ordinarily tend to pull the specimens in the downward direction (in Fig. 3 for example). On this point, the present invention can be readily distinguished from the DeVries device (Fig. 1 for example), by itself or even in combination with Dann et al. Also, the generally C-shaped configuration of the sample passageway of each disclosed embodiment exemplify how the configuration of the sample passageway itself inhibits reflux from gravity.

For these, and other reasons, the invention as defined by claim 47 is believed to be patentable and not rendered obvious by the prior art.

Claims 48 and 49

48. (new) A high specimen yield anti-reflux head for a needle aspiration biopsy device, comprising: a specimen collection well with a floor at its bottom, a needle opening for mounting a needle, and a sample passageway extending from the needle opening to an interior opening located other than at the floor of the collection well in spaced relation to the floor such that a specimen can pass from the needle opening through the sample passageway and be deposited in the collection well from above the floor with collected specimens being spaced from the internal opening.

49. (new) A high specimen yield anti-reflux head for a needle aspiration biopsy device, comprising a specimen collection well with a floor at its bottom, a needle opening for mounting a needle, and a sample passageway extending from the needle opening to an interior opening without passing through the collection well floor, the interior opening being in spaced relation to the collection well floor such that a specimen can pass through sample passageway and be deposited in the collection well from above the floor.

Claim 48 recites that the sample passageway extends from a needle opening to an interior opening that is at a location other than at the floor of the collection, and claim 49 recites that the sample passageway extends from the needle opening to the interior opening without passing through the collection well floor.

In contrast to the present invention, the prior art, alone or in combination, teaches drawing the aspirated material into the collection area by passing it in some form through the bottom of the collection area. For example, DeVries teaches drawing specimens up through the needle 70 and into a central opening 64 that leads directly up into the open interior of the hub 40. Even combining the Dann et al. teaching, which as discussed above applicants believe to be improper, the modified device would have the bent proximal end 17 of the Dann et al. needle 8 extending up through the central opening 64 in the hub 40 of the DeVries device.

Such a device would be clearly distinguishable from that recited in claim 49 since it would pass directly through the bottom or "floor" of the collection area of the hub 40. The modified prior art device is also readily distinguishable from that

recited in claim 48 since the internal opening would still be at the floor of the collection area and not spaced from the collected specimens.

Claim 50

50. (new) A high specimen yielding anti-reflux needle aspiration biopsy device, comprising:
a syringe including a barrel and a piston slidable within the barrel;
a valve for controlling an opening in the syringe barrel;
a hub linked to the valve and defining a specimen collection well; and
a needle mounted to the hub having a shaft with an open pointed tip;
wherein at least one of the hub and needle define a sample passageway extending from the needle tip to an internal opening inside the hub, the internal opening being spaced from a floor of the collection well such that specimens can be deposited in the collection well from above the floor to resist reflux of the collected specimens back into the sample passageway.

Claim 50 discloses a biopsy device with the syringe, valve, hub and needle components expressly delineated. The device has a sample passageway define by one or more of the hub and needle which delivers specimens to the collection well through an internal opening that is spaced from the collection well floor so that specimen can be deposited from above the floor to resist reflux back into the passageway without allowing aspirated material to enter the syringe and be separated from the rest of the sample.

Similar reasoning as stated above applies to claim 50, which is thus is believed to be patentable and not rendered obvious by the prior art.

Dependent Claims

The dependent claims, including the method claims 55-58, are believed to be patentable at least for the reasons stated above with regard to the associated independent claims.

Conclusion

Accordingly, in light of the new claims and the remarks presented herein, the cited prior art is not believed to render the claimed invention unpatentable. Claims

40-58 are thus believed to be allowable, and allowance of these claims is thus respectfully requested.

The above amendments reduced the total claim count to 19 claims, and increase the independent claim count by one (1) from four (4) to five (5). Authorization is hereby given to charge the $100 fee (at the small entity rate) for the additional independent claim to Deposit Account No. 17-0055.

Also, this amendment is accompanying a Request for Continued Examination and a time extension petition requesting a 3-month extension of the response deadline. Authorization for the associated fees (the $395 RCE fee and the $510 3-month extension fee, both at the small entity rate) to be charged to above deposit account is provided in the accompanying documents, and is otherwise given here.

No fees in addition to those enumerated above are believed necessary for consideration of this response. Should any additional fees be needed for full consideration of this amendment, please charge them to the noted deposit account.

Respectfully submitted,

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